K093307

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:
Trade Name: Asept Pleural Drainage System
Common Name: Tunneled Thoracic Catheter and Accessories
Classification: DWM

Equivalent Devices:
Manufacturer: Denver Biomedical (Cardinal Health)
Name: Pleurx Pleural Catheter
510(k) #: K010642/ K011831/ K051084/ K052436

Device Description:
The Asept Pleural Drainage System is a tunneled, long term catheter used to drain accumulated fluid from the pleural cavity to relieve symptoms associated with pleural effusion. The catheter is implanted in the patient's pleural cavity enabling the patient to perform intermittent pleural effusion drainage at home or hospital. The primary components of the system are the Asept indwelling Pleural Catheter and the Asept Drainage Kit. The proximal end of the indwelling catheter has a valve that prevents fluid or air from moving in or out of the pleural space until the valve is breached. The valve can be breached by the Asept Pleural Drainage catheter connected to wall suction or pleurovac or vacuum bottles. The Asept Pleural Drainage System provides patients with a convenient way to relieve pleural effusion symptoms at home.

Intended Use:
The Asept Pleural Drainage System is intended for long-term, intermittent drainage of symptomatic, recurrent, pleural effusions; including malignant pleural effusions and other pleural effusions that do not respond to treatment of the underlying disease.

Performance Data:
In vitro testing was performed on the Asept Pleural Drainage System to assure reliable design and performance in accordance with BS EN 1618-1997. Testing includes leakage, flow rate, tensile strength, and corrosion.

Clinical studies were not deemed necessary since in vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate device.

Biocompatibility:
Materials used in the Asept Pleural Drainage System meet the requirements of ISO 10993 or identical to legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

PFM Medical, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services L.L.C.
1394 25th Street Northwest
Buffalo, Minnesota 55313

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Re: K093307
Trade/Device Name: Asept Pleural Drainage System
Regulation Number: 21 CFR 870.5050
Regulation Name: Patient Care Suction Apparatus
Regulatory Class: II
Product Code: DWM
Dated: October 21, 2009
Received: October 22, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k):

Device Name: **Asept Pleural Drainage System**

Indications for Use: The Asept Pleural Drainage System is intended for long-term, intermittent drainage of symptomatic, recurrent, pleural effusions, including malignant pleural effusions and other pleural effusions that do not respond to treatment of the underlying disease.

Prescription Use ___X_____ AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093307